DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MBSden

Food and Drug Administration
Rockville MD 20857

WARNING LETTER
VIA EXPRESS

JAN 19 2000

Ray NMI Radojevic
Medi-Royale Pastex Inc.
7475 Kimbel Street, Unit #3
Mississauga, Ontario L5S 1E7

Dear Mr. Radojevic,

During an inspection of your firm located in Mississauga, Ontario, on December 6-8, 1999, our investigator determined that your firm manufactures medical adhesive bandages. These bandages are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization as required by 21 CFR 820.20(a).
   Specifically, the firm has failed to establish (i.e. approve and implement) quality procedures including, for example: (a.)Quality Policy, (b.)Management Review, (c.) Training, (d.)Purchasing, (e.)Production and Process Controls, (f.)Corrective and Preventive Actions, and (g.)Non-conforming Product.

2. Processes, whose results cannot be fully verified by subsequent inspection and test, have not been validated and approved according to established procedures as required by 21 CFR 820.75(a). Specifically,
   a.) the current ethylene oxide (EO) sterilization process for plastic strip and flexible bandages (both labeled as sterile) has not been validated to include for example, process qualification and EO residue testing;
   b.) the packaging process for sterile bandages has not been validated to ensure strength and integrity of the seal as well as packaging compatability to the EO process;
   c.) installation and qualification of the adhesive plaster manufacturing machines [redacted] has not been documented; and

d.) the process for manufacturing both plastic strip and flexible bandages consists of multiple steps (including [redacted] the sterile barrier) performed (each) on a single equipment unit that is people dependent. Continuous operator intervention is required, affecting device placement inside the primary sterile barrier. The manufacturing process has not been validated.

3. Incoming product is not adequately inspected or tested to verify conformance to Specifications as required by 21 CFR 820.80(b) Specifically, the "*[redacted]*" Biological Indicators (BI)[redacted] used during EO sterilization have not been tested to verify purported strength. Further, there is no labeling identifying the strength of the BI.

4. Appropriate procedures have not been established (defined and implemented) for controlling environmental conditions as required by 21 CFR 820.70(c). Specifically, procedures for testing bioburden have not been defined and there is no documentation of acceptable bioburden limits.

5. Device History Records (DHRs) are incomplete and fail to demonstrate that the plastic strip and flexible bandages are manufactured in accordance with device specifications as required by 21 CFR 820.184(d). Specifically, sterilization batches *[redacted] and [redacted] identify pressures (for multiple cycle phases) that fail to meet custom sterilizing conditions. The records also fail to specify preconditioning temperature and relative humidity. In addition, there is no documentation that these records were reviewed and approved by the finished device manufacturer.

6. Adequate quality requirements that must be met by contractors are not established as required by 21 CFR 820.50 (a)(1). Specifically, there has been no audit of contract laboratories that provide services for the verification of sterility of plastic strip and flexible bandages.

7. Failure to establish written procedures for the timely and effective communication and identification of Medical Device Reportable (MDR) events as required by 21 CFR 820.198(a)(1) and (3) . Specifically, there is no standard review process or reporting forms on file.

We acknowledge receipt of your December 13, 1999, response to the form FDA 483; however, we request that you provide all information documenting the promised corrections. This should include, but is not limited to written procedures, training records validation protocols and summary reports, new contract agreements concerning sterilization operations, meeting summaries with suppliers, etc. In the meantime, please do not delay in responding to this Warning Letter within the time frame given below.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts

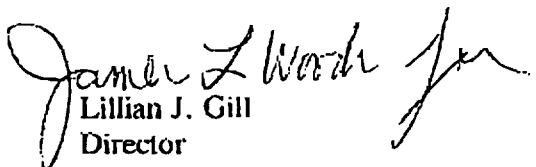
Given the serious nature of these violations of the Act, all adhesive bandages manufactured by Medi-Royale Pastex Inc. of Mississauga, Ontario may be detained upon entry into the United States (U.S.) until these violations are corrected and verified by a passing FDA inspection.

In order to remove the devices from possible detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Rebecca Keenan at 2098 Gaither Rd. Rockville, MD or at (301) 594-4618 or FAX (301) 594-4638.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
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